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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,376	07/28/2001	Shi-You Ding	NREL 01-36	9956

23712 7590 08/01/2002

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,376	Applicant(s) DING ET AL.	
	Examiner Sheridan L. Swope	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,28-36 and 43* is/are pending in the application.

4a) Of the above claim(s) *44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,28-36 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Invention I, Claims 1-15, 28-36, and 43-47 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's cancellation of Claims 16-27, 37-42, and 47-65 in Paper No 9 is acknowledged. Claims 44-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim.

Specification

Page 3 line 14-15: "A Mohagheghi et al., (1986) Int. J. Systematic Bacteriology, 36(3) :435-443." is not a complete sentence. Also see page 3 line 16-17: "M.P. Tucker...". The same problem is found through out the specification. In addition, to not being complete sentences, this manner of citation is unclear; it is not clear as to which statement each citation refers to.

On page 1, the first paragraph under "Background of Invention" the citations A Wiselogel et al and P Bergeron are not complete. The publisher should be provided.

On page 3 paragraph 3 of Amendment A (A5), the specification states that, "In particular, AviIII includes a GH74 catalytic domain (amino acids from about A37 to about G776 and a carbohydrate binding domain type III (CBDIII)(amino acids from about V849 to about at least Q946)". Yet the specification fails to define the motif or conserved sequence by which the glycoside hydrolase domain and the carbohydrate binding domain of cellulases can be identified

and no citation(s) with such information is provided. This information is necessary to evaluate the identity of AviIII. Appropriate citations should be provided.

Fig 2 is not legible.

Table 4: the X-axis should be labeled kDa, not KB.

Claims

Claim 1 is objected to because of the following informalities: AviIII is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

As evidenced by the molecular cloning of Example 1, AviIII of SEQ ID NO: 1 encoded by SEQ ID NO: 2 is naturally occurring substance. Thus, Claims 12 and 13 claim non-statutory subject matter. It is suggested that Claims 12 and 13 be revised to state "An isolated (or purified) thermostable AviIII peptide ..."

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 7, and 8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiply dependent claim may not depend from another multiply dependent claim. See MPEP § 608.01(n).

Claims 4, 5, 7, and 8 are also objected to because a claim cannot be dependent on itself, as is the current Claim 4. Claims 5, 7, and 8 are also objected to as being dependent on Claim 4.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear in Claim 9 whether the claimed invention is a composition comprising the peptide of Claim 1 plus a protein comprised of the polypeptides represented by SEQ ID NO: 3 and 4 or whether the invention is a composition comprising a protein comprised of the polypeptides represented by SEQ ID NO: 3 and 4. If the latter is the meaning, suggested claim language for Claim 9 would be: The composition of Claim 1 wherein said AviIII protein comprises the polypeptides represented by SEQ ID NO: 3 and SEQ ID NO: 4." Claims 10 and 11 are indefinite for the analogous reason and should also be corrected.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 claims a peptide having a sequence of SEQ ID NO: 2. But SEQ ID NO: 2 represents a polynucleotide sequence. It is suggested that the applicants use the phrase "peptide... encoded by the polynucleotide of SEQ ID NO: 2".

The following terms should be defined at their first appearance:

Claim 1: GH

The following terms should not be abbreviated as they are only used one time:

Claim 33: GST; OmpA

Claim 1 is missing an article: "...comprising a catalytic domain GH74 and **a/the** carbohydrate binding domain..."

Claim 10: Do the inventors mean to claim "The composition... comprising... a nucleic acid sequence having **at least** about 70% sequence identity..."? This question is also relevant to Claims 11, 28, and 29.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14, 15, 28-36, and 43 while being enabled for the peptide of SEQ ID NO: 1 or encoded by SEQ ID NO: 2, or compositions thereof, do not reasonably provide enablement for any thermostable AviIII polypeptide having a catalytic glycoside hydrolase domain and a carbohydrate binding domain or any polypeptide comprising a sequence of 70% identity to SEQ ID NO: 2, 4, or 5, or compositions thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1, 14, and 15 are so broad as to encompass any composition comprising any thermostable AviIII polypeptide having a catalytic glycoside hydrolase domain and a carbohydrate binding domain. The scope of this claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired thermostable cellulase activity and carbohydrate binding activity requires a knowledge of and guidance with regard to which amino acids in the protein's

sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO 1 and the peptide encoded by the nucleotide sequence of SEQ ID NO 2.

Claims 2-5 further define the polypeptide of Claim 1 as including a linker and signal sequence, a GH74 domain of 730-760 amino acids, a CBD of 80-160 amino acids, and a CBD of 154 amino acids, respectively. Although these Claims provide more information about the invention, the specification does not support their enablement for the same reasons described for Claims 1, 14, and 15.

Claims 6-9, 28-36, and 43 further define the polypeptide of Claim 1 as having a CH74 domain of SEQ ID NO: 3 (Claim 6), a CBD of SEQ ID NO: 4 (Claim 7), a CBD of SEQ ID NO: 5 (Claim 8), and SEQ ID NO: 3 plus SEQ ID NO: 4 (Claim 9), and 70% (Claim 28) or 90% (Claim 29) identity to these sequences, and fusion proteins (Claims 30-36) and compositions thereof (Claim 43). Although these claims define the sequences of certain domains of the protein, they are not enabled as, the remaining sequence of each protein encompassed by these claims is not defined.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable. In addition, one skilled in the art

would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the Claim 1which, encompasses all polypeptides that encode a protein having thermostable cellulase activity with carbohydrate binding. The specification does not support the broad scope of Claims 2-9 which, encompasses all polypeptides that encode a protein having thermostable cellulase activity and carbohydrate binding with one specific subdomain defined in terms of function, size, or sequence. The specification does not support the broad scope of Claims 1-9, 14, 15, 28-36, and 43 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the enzymatic or carbohydrate binding activity of AviIII; (B) the general tolerance of the enzymatic and carbohydrate binding activity of AviIII to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of thermostable AviIII enzymes with an enormous number of amino acid modifications. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and

improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to compositions comprising a genus of thermostable AviIII polypeptides from any source having a glycoside hydrolase catalytic domain and a carbodydrate binding domain. The specification teaches the structure of only a single representative species of such polypeptides. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a cellulose enzyme. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 28-36 and 43 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of isolated polypeptides comprising either SEQ ID NO:1, 3, 4, or 5, or compositions thereof, or any polypeptide comprising a sequence of 70% identity to SEQ ID NO: 1, 3, 4, or 5, or compositions thereof.

The specification does not contain any disclosure of the function of all polypeptides claimed. The genus of proteins that comprise these polypeptides is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims, including partial protein sequences. The specification discloses only a single species of the claimed genus which, is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 28, 29, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Tucker et al, 1992 or Adney et al, 1994 as evidenced by Klarskov et al 1997, Harrison et al, 1998, and Adney et al, 1998. Both Tucker et al (Abstract) and Adney et al, 1994 (Example 7) teach the isolation of a 156-203kDa thermostable cellulase from Acidothermus cellulolyticus. Adney et al, 1994 also teach that Acidothermus cellulolyticus expresses three thermostable cellulases, the one of 156-203kDa and two low molecular weight enzymes of 57-74kDa and 50-70kDa (col 7 lines 56-63). The deduced molecular weight for the AviIII cellulase of the present application, based on SEQ ID NO: 1, is approximately 105kDa, smaller than the size of the high molecular weight cellulase taught by Tucker et al and Adney et al, 1994. However, cellulases are secreted proteins that are known to be highly glycosylated as shown by Klarskov et al (page

149 paragraph 2-page 150 and Figs 5 & 6), Harrison et al (Abstract), and Adney et al, 1998 (column 6, lines1-5) and the sequence of SEQ ID NO: 1 indicates that AviIII is glycosylated at amino acid residues N^{394}-R-S, N^{633}-G-T, and N^{880}-D-S. Thus, the final size of the secreted AviIII protein would be larger than 105kDa. Furthermore, since Adney et al teach that Acidothermus cellulolyticus expresses only three cellulases, AviIII would be the high molecular weight enzyme.

Claim 1 of the present application claims a thermostable peptide, AviIII, comprising a glycoside hydrolase domain and a carbohydrate binding domain. In the present application, Claims 2-9, 12, 13, 28, 29, and 43 claim additional limitations including a linker and signal sequence, a GH74 domain of 730-760 amino acids, a CBD of 80-160 amino acids, a CBD of 154 amino acids, a CH74 domain of SEQ ID NO: 3, a CBD of SEQ ID NO: 4, a CBD of SEQ ID NO: 5, SEQ ID NO: 3 and 4, SEQ ID NO: 1, SEQ ID NO: 2, any or all of SEQ ID NO: 3, 4, 5, 1, or 70% or 90% thereof. These limitations are not specifically taught by Tucker et al, or Adney et al, 1994; however, they are inherent to the thermostable endoglucanase isolated by Tucker et al, and Adney et al 1994. Therefore, Claims 1-13, 28, 29, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Tucker et al, 1992 or Adney et al, 1994 as evidenced by Klarskov et al 1997, Harrison et al, 1998, and Adney et al, 1998.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohagheghi et al, 1986 in view of Berghem et al, 1976 and Katz et al, 1968. Mohagheghi et al teach the isolation of a thermostable acidophilic cellulolytic bacterial strain they named Acidothermus cellulolyticus. Mohagheghi et al, do not teach the isolation of cellulases from Acidothermus cellulolyticus. Berghem et al teach the isolation of cellulases from Trichoderma viride (Abstract). It would have been obvious, to a person of ordinary skill in the art at the time Mohagheghi et isolatied the thermostable acidophilic cellulolytic bacterial strain Acidothermus cellulolyticus, to isolate a thermostable avicelase from Acidothermus cellulolyticus. Motivation to do so derives from the fact that "there is a need within the art to generate alternative cellulase enzymes capable of commercial scale processing of cellulose" (page 2 of Amendment 1, insert A1 of this application) and because elevated temperatures enhance the susceptibility of cellulose to degradation, as taught by Katz et al, 1968 (Fig 1)). Therefore, Claims 1-13, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohagheghi et al, 1986 in view of Berghem et al, 1976 and Katz et al, 1968.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al, or Adney et al, 1994 in view of Vollmond et al, 1999 and Katz et al, 1968. The cellulase taught by Tucker et al and Adney et al, 1994 is described above. Neither Tucker et al nor Adney et al, 1994 teach an industrial mixture, containing the high molecular weight cellulase, that is suitable for degrading cellulose. Vollmond et al teach industrial mixtures containing an acidophilic cellulase for degrading cellulose-containing fabrics (Examples 2 and 3). Since the high molecular weight cellulase of Tucker et al (Example 7) and Adney et al, 1994 (Example 7) can

also degrade cellulose, it would be obvious to a person of ordinary skill in the art to make an industrial mix containing the cellulase of Tucker et al, and Adney et al, 1994. Motivation to do so derives from the fact that "there is a need within the art to generate alternative cellulase enzymes capable of commercial scale processing of cellulose" (page 2 of Amendment 1, insert A1 of this application). Furthermore the fact that the high molecular weight enzyme of Tucker et al, and Adney et al, 1994 is thermophilic, would provide the advantage of hydrolysis at elevated temperatures which, is conducive to degradation of cellulose as discussed by Katz et al, 1998 (Fig 1). Thus, Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al, or Adney et al, 1994 in view of Vollmond et al, 1999 and Katz et al, 1968.

Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al and Adney et al, 1994 in view of Gal et al, 1997 and Ausbel et al, 1996. The cellulase taught by Tucker et al and Adney et al, 1994 is described above. Neither Tucker et al nor Adney et al, 1994 teach a fusion protein comprised of cellulase subdomains and a heterologous peptide. Gal et al teach a fusion protein comprised of the cellulose binding-domain of a cellulase linked to the glutathione S-transferase peptide (Abstract). Furthermore, it is common in the art to prepare fusion proteins whereby the protein of interest is linked to a heterologous protein (Ausbel 1996). It would have been obvious to a person of ordinary skill in the art to make a fusion protein in which domains of the cellulose of Tucker et al and Adney et al, 1994 were linked to heterologous proteins. One would be motivated to do so to provide a means to easily isolate the fusion protein by affinity chromatography (Ausbel 1996) or to assess binding of enzyme subdomains to substrates or regulators (Gal et all, 1997). Therefore, Claims 30-33 are rejected under 35

U.S.C. 103(a) as being unpatentable over Tucker et al and Adney et al, 1994 in view of Gal et al, 1997 and Ausbel et al, 1996.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al 1992 or Adney et al, 1994 in view of Bates et al, 1997. The cellulose of Tucker et al and Adney et al 1994 is described above. Neither Tucker et al nor Adney et al teach binding of the thermostable cellulase from Acidothermus cellulolyticus to cellulose paper. However, Bates et al, teach cellulase bound to cellulose paper (Abstract). It would have been obvious to a person of ordinary skill in the art to bind the enzyme of Tucker et al and Adney et al, 1984 to cellulose paper, as taught by Bates et al. The motivation to do so derives from the advantage of using such a complex as a matrix for identifying agents that bind and/or modulate the high molecular weight thermostable cellulase of Tucker et al and Adney et al, 1994. Therefore, Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al 1992 or Adney et al, 1994 in view of Bates et al, 1997.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al or Adney et al, 1994 in view of Scott et al, 1994. The teachings of Tucker et al and Adney et al, 1994 to isolate a thermostable cellulase are described above. Tucker et al and Adney et al, 1994 did not teach a composition comprising their thermostable cellulase and a carrier. However, it is common practice to combine an enzyme with a carrier for therapeutic, scientific, and industrial applications. Scott et al teach an industrial composition comprising a protease and a carrier (column 4, lines 49-58). Thus, it would have been obvious, to a person of ordinary skill in the art to combine the enzymes of Tucker et al, and Lastick et al 1984 with a carrier. Motivation to do so derives from the desire to stabilize the enzyme and to dilute it with an appropriate liquid or

solid. Thus, Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al or Adney et al, 1994 in view of Scott et al, 1994.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600